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**REMARKS**

The Final Office Action mailed June 28, 2005, has been carefully reviewed and Applicants note with appreciation the identification of allowable subject matter.

By this Amendment, which is being filed concurrently with an RCE, Applicants have amended claim 1, and added claim 27. Claims 1, 3-7, 9-13, 15, 17-19 and 21-27 are pending in the application, and claims 1, 25, 26 and 27 are independent. Applicants also submit herewith the Declaration of Truels Sterm Larsen to provide evidence of non-obviousness in accordance with 37 C.F.R. 1.132. In view of the above amendments, the Declaration, and the following remarks, favorable reconsideration is respectfully requested.

The Examiner rejected claims 1, 3-6, 12, 17, 23 and 24 under 35 U.S.C. 102(e) as being anticipated by Delmore. Under 35 U.S.C. 103(a), the Examiner rejected claims 7, 9 and 21 as being unpatentable over Delmore in view of Malloul, rejected claim 10 as being unpatentable over Delmore in view of U.S. Patent No. 5,181,905 to Flam, rejected claims 11 and 13 as being unpatentable over Delmore in view of U.S. Patent No. 6,168,800 to Dobos, and rejected claim 15 as being unpatentable over Delmore in view of Dobos and further in view of Marcussen. Claims 18, 19 and 22 were objected to as being dependent on a rejected base claim, but the Examiner stated that claims 18, 19 and 22 would be allowable if

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rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 25 and 26 are allowed.

As clarified in amended claim 1, the present invention is directed to a pressure relieving dressing for a wound, the dressing having an absorbent element encircled by a substantially non-absorbing pressure distributing element, both of which are in contact with the skin when the dressing is applied thereto. The absorbent element is *inset within* the pressure distributing element such that the absorbent element extends, *from its skin-contacting surface*, at least partly *through the thickness* of the pressure distributing element. This is not shown by Delmore.

Delmore is directed to a self-adhering elastic bandage that may be compressively wrapped around a wound, the elastic portion thereof having a compressive force when extended, so as to apply pressure to the wound. As stated by Mr. Larsen in paragraph 8 of his Declaration, "in no way can such a compressive or pressure-applying construction be interpreted to constitute a pressure distributing element." He goes on to state that the material from which the Delmore bandage is made does *not* function to *relieve* both static pressure and sudden impacts as it would provide no shock-absorbing effect for the patient when walking. Nor is there anything to suggest the inclusion of a pressure

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distributing element in the Delmore bandage as this would be contrary in purpose to the pressure-exerting construction of Delmore.

Furthermore, Delmore does not disclose an absorbent element that is *inset within* and therefore extends *into* the thickness of the pressure distributing element. As already noted, the effectiveness of the Delmore bandage depends upon its ability to apply pressure *to* the wound. To accomplish this, it is important that the ability of the elastic substrate to expand and contract is not compromised by the bonding of the absorbent pad thereto. Therefore, according to the embodiment shown in Figure 3 of Delmore and discussed at column 7, the absorbent pad 32 is bonded to the elastic substrate with an adhesive layer 34 that is applied in a *thin* strip "in order to minimally inhibit" such expansion and contraction (column 7, lines 28-31). Delmore specifically states that the use of a *thin* strip "allows the elastic substrate to expand and contract by sliding past the pad" (column 7, lines 31-33). As substantiated in paragraph 11 of the enclosed Declaration, this function would be significantly altered were an absorbent element to be *inset within* the thickness of the elastic substrate.

In sum, Delmore lacks both a *pressure distributing* element and an absorbent element which is inset therein so as to

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extend through at least part of the thickness thereof, as set forth in claim 1. Accordingly, claim 1 is clearly not anticipated by Delmore and, for the reasons just discussed and as substantiated by Mr. Larsen's Declaration, is not obvious in view thereof either.

Malloul also does not teach an absorbent element that extends *from the skin contacting surface* at least partly through the thickness of the pressure distributing element. Instead, Malloul teaches an inelastic support 1 having an absorbent or padded element 3 positioned *between* two shock-absorbing pads 4. The shock absorbing pads 4 engage healthy skin on either side of a wound while defining a free intermediate space that surrounds the wound *without touching it* (see the Abstract). Hence, while the element 3 *spans the distance between* the pads 4 it cannot be said that the padded element 3 extends *into or through the thickness* of the shock-absorbing pads 4. Nor is there anything to suggest insetting of the absorbent element 3 so that it extends from the skin into the thickness of the pressure distributing pads as this would both interfere with the disclosed manner in which the dressing is secured to the healthy skin by adhesive portion 2, and also be in contradiction to the express purpose of protecting the wound from contact.

As stated by Mr. Larsen in his Declaration, there would also be no motivation to combine Malloul with Delmore. As

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summarized in paragraphs 10 and 11 of the Declaration, the structurally stiff shock-absorbing pads of Malloul could not be incorporated fully or partly into the elastomer substrate of Delmore without negatively impacting the compressive properties of the latter.

Further evidence of the non-obviousness of claim 1 is provided by the article entitled "Reduction of Plantar Pressure using a Prototype Pressure-Relieving Dressing" by Carine H.M. van Schie, et al. ("the van Schie article") which is attached to Mr. Larsen's Declaration as Attachment B. As discussed by Mr. Larsen in paragraphs 12-16 of his Declaration, the van Schie article summarizes the results of a study in which diabetic patients were provided with a prototype of the claimed invention to assess the effectiveness of the prototype in providing pressure-relief in a wound dressing. The van Schie article not only substantiates the need for a dressing having pressure-relieving properties but also that "currently there is no dressing available that contains specific pressure-relieving qualities" (see the first paragraph of the van Schie article and as quoted in paragraph 14 of the Declaration). This long-standing but unmet need provides clear evidence that the claimed invention, in meeting this need, is patentable over the prior art.

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For at least the foregoing reasons, claim 1 is neither anticipated by nor obvious in view of Delmore alone, or in combination with Malloul, and is patentable thereover. Applicants request that the Examiner fully consider the foregoing remarks in view of Mr. Larsen's Declaration and the van Schie article attached thereto, and withdraw the rejection of claim 1 as amended herein.

Claims 3-7, 9-13, 15 and 17-19 are also in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein.

More particularly, in regard to claim 9, Applicants request reconsideration by the Examiner of what is taught by Malloul as compared with the presently claimed invention. Specifically, the holes shown in Figures 3 and 4 of Malloul, when they are included, provide *aeration* to the support 1 (see the Abstract). To provide this function, the holes must extend *through* the outer layer. As provided in claim 9 of the present invention, by contrast, the indentations in the pressure distributing element are for the purpose of flexibility and *do not extend through* the overlying top layer (see page 9, lines 18-23; page 16, lines 12-16).

This limitation of the extent of the indentations does not appear to have been fully considered by the Examiner in rejecting claim 9. Specifically, the Examiner stated that the

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"indents could be used to allow air to pass", which seems to overlook that according to claim 9 the indents do *not* extend through the top layer, i.e., air flow is obstructed by the intact top layer. Further, the Examiner stated that "Delmore discloses indentations (*the outer layer is porous*)" (emphasis added). Instead of supporting the Examiner's position that claim 9 is obvious in view of Delmore, this statement actually distinguishes claim 9 from Delmore as in claim 9 the outer layer is *not* perforated. Accordingly, the Examiner's reconsideration and withdrawal of the rejection of claim 9 is requested. Claim 21 is also in condition for allowance for at least the same reasons as claim 9.

Claims 18, 19 and 22 are allowable in accordance with the Examiner's identification of allowable subject matter therein.

Reconsideration of claims 23 and 24 is also requested as it is not clear to Applicants what structure in Delmore is being relied upon to reject these claims. As set forth in claim 23, the present invention may include an elongated top layer opposite the skin-contacting surface, the elongated top layer *extending beyond an outer edge of the pressure distributing element to form a flange*. Delmore does not disclose an elongated top layer forming a flange. To the extent that the Examiner may be relying upon the

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tab 36, such tab is not an elongation of the top layer but only a small coated area of the elastic substrate itself (see column 7, lines 33-38). Being *part of* the substrate, it does not, and indeed logically cannot, extend beyond an outer edge of itself. Hence, claim 23 is neither anticipated by nor obvious in view of Delmore.

Claim 24 further defines the flange of claim 23, stating that the flange encircles the skin-contacting portions of the absorbent element and the pressure distributing element. There is no comparable structure in Delmore. In addition, claim 24 states that adhesive is applied to the flange while the encircled absorbent and pressure distributing elements are non-adhesive. This is in no way shown by the tab of Delmore which is both *non-adhesive* and *non-encircling*, being limited to a single edge on one side of the self-adherent elastic substrate. Reconsideration and withdrawal of the rejection is therefore respectfully requested and, if the rejection is maintained, Applicants request clarification as to the basis therefor in the prior art.

New claim 27 represents the subject matter of claim 22 rewritten in independent form to substantially include the limitations of the underlying claims and is in condition for allowance in accordance with the Examiner's identification of allowable subject matter therein.



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Accordingly, with this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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